

K093425

FEB 24 2010

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EXHIBIT 2
510(K) SUMMARY

Submitter: MAKO Surgical Corp.
Address: 2555 Davie Road, Fort Lauderdale, FL, 33317
Phone number: 954-927-2044 x 605
Fax number: 954-927-0446
Contact Person: William F. Tapia
Date Prepared: November 1, 2009
Device Trade Name: Robotic Arm Interactive Orthopedic System - THA (RIO - THA)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO

Substantial Equivalence Claimed To: RIO - THA is substantially equivalent to MAKO Surgical's RIO - Hip (K091998), Tactile Guidance System v2.0 (a.k.a. RIO, K081867), Brainlab's Vectorvision Hip (K010602, K040368, K052213, K072716), Orthosoft's Navitrack System - Total Hip Replacement (K022364), Stryker's Navigation System-CT Based Hip Module (K050615) and Stryker's Navigation System-Hip Module (K022365).

Description: The main RIO platform includes an optical detector, computer, dedicated instrumentation, operating software, tools and accessories, drill system, and a robotic arm. The system's architecture is designed to support two main surgical applications: knee procedures (per the predicate device K081867) and THA procedures (per RIO-THA described in this 510(k) submission). With application specific hardware and software, it provides stereotactic guidance during minimally invasive orthopedic surgical procedures by using patient CT data to assist a surgeon with presurgical planning and interpretive/intraoperative navigation. RIO's robotic arm, once configured for a specific application (knee or hip), can serve as surgeon's "intelligent" tool holder or tool guide by passively constraining the preparation of an anatomical site for an orthopedic implant with software-defined spatial boundaries.

Summary of Technological Characteristics Compared to Predicate Devices:

The technological characteristics of RIO-THA compared to the predicate devices are listed below:

Table with 6 columns: Technological Characteristics, RIO-THA, RIO (K081867), Brainlab Vectorvision (VV), Orthosoft Navitrack System, and Stryker Navigation System. Rows include Major Components, Tools/accessories, and Images Use.

Performance Data:

System level verification testing was performed in the laboratory with RIO-THA using sawbone models to evaluate setup, registration, and overall accuracy and functionality of the system in supporting THA. Further testing was performed with RIO-THA using cadaveric material where post-operative x-rays were obtained and evaluated in order to validate the system's intended use. The results of these tests satisfied all required acceptance criteria and were found to support substantial equivalence of the RIO-THA to the predicate devices.

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Intended Use/Indications for Use:

The Robotic Arm Interactive Orthopedic System (RIO) is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The RIO is indicated for use in surgical knee and hip procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include:

- Unicondylar knee replacement and/or patellofemoral knee replacement
- Total hip arthroplasty (THA)



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Mako Surgical Corp.
% Mr. William F. Tapia
Director, Regulatory Affairs
2555 Davie Road
Fort Lauderdale, Florida 33317

FEB 24 2010

Re: K093425

Trade/Device Name: Robotic Arm Interactive System - THA
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 22, 2010
Received: January 25, 2010

Dear Mr. Tapia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 - Mr. William F. Tapia

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

For 
Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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EXHIBIT 1

INDICATIONS FOR USE

510(k) Number (if known): K093425

Device Name: RIO-THA

Indications for Use:

The Robotic Arm Interactive Orthopedic System (RIO) is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The RIO is indicated for use in surgical knee and hip procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include:

- o Unicondylar knee replacement and/or patellofemoral knee replacement
- o Total hip arthroplasty (THA)

Prescription Use X

OR

Over-the-Counter Use

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number

K093425